UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

Date: **August 25, 2020**

SUBJECT: Risk Assessment for the New Active Ingredient Sodium Benzoate as a Material Preservative in Industrial and Household Products Including those with Indirect Food Contact

PC Code: 009103	DP Barcode: D454105, D447340 (parent)
Decision No.: 540829	Registration Number: 91212-R
Risk Assessment Type: PRIA RA	Case No: 4013 and 5107
TXR No.: NA	CAS No.: 532-32-1

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This document provides the human health and ecological risk assessment conducted in support of the new active ingredient PRIA registration of sodium benzoate as an in-container material preservative for the control of bacteria, mold, and fungi in industrial and household products at a maximum level of 3% by weight.

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EXECUTIVE SUMMARY

Emerald Kalama Chemical, LLC has submitted a request for the new end-use product (EP), tradename Kalaguard® SB (EPA Reg. No. 91212-R) containing the proposed new active ingredient (AI), sodium benzoate. This product is intended to be used as an in-container material preservative for the control of bacteria, mold, and fungi in industrial and household products at a maximum level of 3% by weight. The proposed label (drafted June 11, 2020) is attached in Appendix A. This product is classified as a new active ingredient (AI) and a new indirect food use.

Human Health Risk Summary

For the proposed uses of Kalaguard® SB, risk from oral and dermal exposures are expected to be minimal. Sodium benzoate (the proposed new AI) is considered "Generally Recognized as Safe" (GRAS) by the Food and Drug Administration (FDA) and any exposures in these pathways would be well below the GRAS limit; therefore, endpoints were not set for oral and dermal exposures. A point of departure could not be determined for inhalation; the effects seen at the highest dose tested (1.2 mg/L; body weight loss and mortality) were above the limit dose of 1.0 mg/L which is not relevant for risk assessment.

Ecological Risk Summary

Sodium benzoate is the salt of benzoic acid and will immediately dissociate to form benzoic acid in an aqueous environment; therefore, the environmental fate data for sodium benzoate is essentially that of benzoic acid.

Based on the proposed uses of Kalaguard® SB, environmental exposure to sodium benzoate and benzoic acid is expected to be minimal. Most end-use products cited on the proposed label are inherently indoor uses and will result in negligible environmental exposure. Although some products may travel down-the-drain into a municipal wastewater treatment plant (WWTP), environmental exposure is expected to be minimal because sodium benzoate is readily biodegradable, concentrations will be diluted within the waste stream, and releases would not be concentrated in any specific geographic location. Additionally, the Agency is making a "no effect" determination under the Endangered Species Act (ESA) based on low expected environmental exposure.

The available ecotoxicity data indicate sodium benzoate is practically non-toxic to birds and moderately to practically non-toxic to freshwater fish and invertebrates. Additionally, it shows toxicity to aquatic plants at concentrations greater than 1 ppm.

INTRODUCTION

Case Overview

The risk assessment conducted for this action under the Pesticide Registration Improvement Act (PRIA) is for the new active ingredient (AI) sodium benzoate (PC 009103) with indirect food use. The product (EPA Reg. No.91212-R) is an end-use product and will be used as a material preservative in industrial and household products. Although sodium benzoate was previously registered in the 1960s to 1980s first by the United States Department of Agriculture and then the US EPA, the previously registered products were cancelled.

Sodium benzoate, benzyl benzoate (PC 009501), and benzyl alcohol (PC 009502) all degrade to benzoic acid (PC 009101) and all four AIs were originally considered within the Registration Review case Benzoic Acid and Derivatives (case number 4013). By the time of the 2007 Reregistration Eligibility Decision (RED), only benzyl benzoate, an insecticide, had active product registrations which were subject to reregistration. In 2005, benzoic acid was re-registered as an antimicrobial in food grade lubricating oil and given the new case number 5107. Human exposure to residues of benzoic acid from pesticidal sources is expected to be minimal compared to naturally occurring levels in food (especially in fruits), as well as the direct food-additive uses, pharmaceutical uses, and cosmetic uses regulated by the Food and Drug Administration (FDA). Both benzyl benzoate and benzoic acid are presently undergoing registration review. Information on these cases is available at www.regulations.gov in docket EPA-HQ-OPP-2015-0597 for benzyl benzoate and EPA-HQ-OPP-2010-0692 for benzoic acid.

Ingredient Profile

Pure sodium benzoate is a white crystalline powder that is formed by the reaction of benzoic acid with sodium hydroxide (NaOH). The formulated product is formulated as a particle that is 92% ≥ 212 µm (MRID 51053901). In an aqueous environment, sodium benzoate will immediately dissociate to form benzoic acid. Table 1 and 2 below lists the chemical identity and physical properties of sodium benzoate and benzoic acid.

Table 1. Chemical Identity of Sodium Benzoate and Benzoic Acid

Chemical Name	Sodium Benzoate	Benzoic Acid
PC Code	009103	009101
CAS Number	532-32-1	65-85-0
Smiles Code	[O-]C(=O)c1ccccc1.[Na+]	[O-]C(=O)c1ccccc1
Molecular Formula	$C_7H_5O_2Na$	$C_7H_6O_2$
Molecular Weight (g/mol)	144.1	122.1

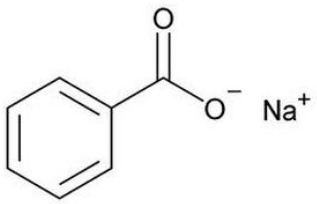
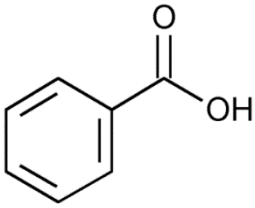
Chemical Name	Sodium Benzoate	Benzoic Acid
Molecular Structure		

Table 2. Physical Properties of Sodium Benzoate and Benzoic Acid

Chemical Name	Sodium Benzoate	Benzoic Acid
Log Kow	-2.13	1.87
Water Solubility (25ºC)	$5.56x10^2$ g/L	3.4 g/L
Vapor Pressure (25ºC)	$2.9x10^{-12}$ mm Hg	7×10^{-4} mm Hg
Melting Point	436ºC	252ºF (122.4ºC)
Density	1.50 g/cm^3	1.27 g/cm^3 (15ºC)

Source: EpiSuite, HSDB, and USEPA, 2010c

Use Pattern

Kalaguard® SB (EPA Reg. No.91212-R) is a granular formulation of sodium benzoate which is proposed for use as an in-container material preservative for the control of bacteria, mold and fungi in industrial and household products including detergents, fabric softeners, soaps, liquid cleaners, furniture care, floor care, cleaning wipes, shampoos, leather care, aerosols, coatings, inks, adhesives, silicones, surfactants and other water-based products requiring preservation. It is to be added to the final product at a maximum level of 3% by weight. Additionally, the proposed label instructs occupational users to add the product at any convenient time during the manufacturing process. For more label information see Appendix A.

Label Recommendations

The label lists “shampoos” as an example of a household product to be treated. The specific shampoo type (*i.e.,* carpet, hair, or pet) should be clarified.

HUMAN HEALTH RISK ASSESSMENT

Anticipated Exposure Pathways

The anticipated human health exposure pathways for Kalaguard® SB (EPA Reg. No.91212-R) can occur via the oral, dermal, and inhalation routes. Oral exposure occurs via indirect food contact when sodium benzoate is used as a materials preservative in household cleaning products that are used to clean kitchen countertops and incidental oral exposure to children during hand-to-mouth activities while playing on treated floors*, etc*. Dermal and inhalation routes of exposure occur when consumers are spraying/wiping/moping with household cleaners preserved with

sodium benzoate or children contacting treated floors. There is also potential for dermal and inhalation occupational exposure to workers adding the product to the materials for preservation. There is the potential for occupational handler inhalation exposure during the application of sodium benzoate products for surface treatments using sprays, mops, or wipes.

Hazard Characterization and Dose-Response Assessment

The database for sodium benzoate is incomplete but is considered adequate for the purpose of this risk assessment. It should be noted this risk assessment applies only to this formulation of sodium benzoate and cleaning applications at the specific rates that have been assessed here and would need to be re-assessed if the physical form of the active ingredient or the application rate changes.

Toxicology Studies Available for Analysis

A number of the studies submitted for support of this registration were obtained from the open scientific literature. OPP has published guidance regarding the adequacy of scientific literature studies submitted in support of a human health risk assessment (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-considering-and-using-open-literature). To be considered adequate for risk assessment purposes, information from open literature should be presented as a full article and not a summary. Not all studies listed as required in accordance with the current 40 CFR Part 158W Toxicology Data Requirements are available; however, due to the long history of use, exposure, and low hazard of sodium benzoate, the existing toxicity database is sufficient, and no additional data are needed at this time. Sodium benzoate is part of the benzoic acid registration review case (#4013) which also includes benzoic acid and benzyl alcohol. The Agency applied all available toxicity information to all members of the chemical case (USEPA, 2007) because of their relatedness. Sodium benzoate, benzyl benzoate (PC 009501), and benzyl alcohol (PC 009502) all degrade to benzoic acid (PC 009101). The following studies were reviewed for qualitative purposes for this registration.

- 90-day oral toxicity study in rats (MRID 50471420-Deuel, H.J., *et al.* 1954.)
- 90-day oral toxicity study in rats and carcinogenesis study in rats (MRID 50471427-Sodemoto, Y. and M. Enomoto. 1980.)
- 10-day oral toxicity study in rats (MRID 50471427-Fujitani, T. 1993.)
- 90-day dermal toxicity study in rats (MRID 43566901)
- 28-day inhalation study in rats (MRID 50680903)
- *In vitro* mammalian gene mutation (MRID 51021401-National Toxicology Program (NTP), 1990. Toxicology and Carcinogenesis Studies on Benzaldehyde in F344 rats and B6C3F1 mice)

- *In vitro* mammalian gene mutation (MRID 43148604-NTP, 1989. Toxicology and Carcinogenesis Studies on Benzyl Alcohol in F344 rats and B6C3F1 mice)
- Reverse mutation assay (MRID 50471433-Prival, M. J., *et al*. 1991.)
- Reverse mutation assay (MRID 50471433-Haworth, S.R., *et al.* 1979)
- *In vivo* cytogenetics (MRID 50471435)
- Metabolism and pharmacokinetics (MRID 50471436-Kubota, K, and T. Ishizaki. 1991)

Summary of Toxicological Effects

After oral ingestion of benzoic acid and sodium benzoate, undissociated benzoic acid is rapidly absorbed from the gastrointestinal tract in mammals (IPCS, 2000). In humans, the peak plasma concentration is reached within 1–2 hours. After oral uptake, benzoate is metabolized in the liver by conjugation with glycine, resulting in the formation of hippuric acid (US FDA, 1973; IPCS, 2000). The rate of biotransformation in humans is high. After oral doses of 40, 80 or 160 mg sodium benzoate/kg body weight, the transformation to hippuric acid was independent of the dose - about 17-29 mg/kg body weight per hour, corresponding to about 500 mg/kg body weight per day (Kubota & Ishizaki, 1991). Hippuric acid is rapidly excreted in urine.

There are no acute category designations for sodium benzoate; instead, the determinations for benzoic acid were used. Benzoic acid has low acute toxicity via the oral (Toxicity Category III), dermal (Toxicity Category IV), and inhalation routes of exposure (Toxicity Category IV). Acute eye irritation resulted in classifying benzoic acid as Toxicity Category I.

The Agency reviewed various oral mammalian toxicity studies submitted by the registrant that were taken from the scientific literature using sodium benzoate or benzoic acid (Deuel, 1954; Sodemoto and Enomoto, 1980; Fujitani, 1992). No adverse effects were seen below the limit dose (1000 mg/kg/day) and thus the oral route is not of concern. Two dermal studies were submitted by the registrant to support the registration of this product. Effects were only seen at or above the limit dose of 1000 mg/kg/day (MRID 50680901, MRID 43566901).

A 28-day inhalation study in rats was deemed acceptable/non-guideline by the Agency (MRID 50680903). Although the study authors did not investigate portal of entry effects, there did not appear to be much evidence of such (reddish discharge around the nares was noted). Decreased body weight and mortality were only observed above the limit dose of 1.0 mg/L, which was deemed not relevant for risk assessment.

The Agency lacks an acceptable study for neurotoxicity (OCSPP 870.6200 or 870.6300). The open literature study (MRID 50471430) submitted was deemed unacceptable to support this requirement given that only activity and brain chemistries in the offspring were measured. While the Agency lacks an acceptable study for neurotoxicity, other short- and long-term studies

submitted by the registrant and categorized as acceptable for qualitative purposes did not demonstrate neurotoxic effects below 1000 mg/kg/day (the limit dose) (Deuel, 1954; Sodemoto, 1980; Ulrich, 1981).

Sodium benzoate is negative in the reverse mutation assay performed in the various *Salmonella thyphimurium* strains and *Escherichia coli* strain WP2 (Prival *et al*., 1991). Sodium benzoate is also negative in cytogenetic and dominant lethal assays (MRID 50471435; Haworth, 1979). However, the structurally related benzaldehyde, benzyl alcohol, and benzyl acetate all tested positive in the L5178Y mouse lymphoma cell forward mutation assay and increased sister chromatid exchanges in CHO cells in both the presence and absence of metabolic activation (NTP, 1990; NTP, 1989; NTP 1993). The National Toxicology Program (NTP) conducted two-year toxicology and carcinogenesis studies on benzyl alcohol (1989) and benzaldehyde (1990) and found no definitive conclusions of carcinogenicity could be made because some of the studies were negative and some of the studies were positive.

Consideration of Toxicological Effects in Children

Children can be exposed to end-use-products composed of Kalaguard® SB (EPA Reg. No.91212-R) when used as a materials preservative via the oral route. However, due to the lack of toxicity via the oral route from exposure to sodium benzoate, there are no risks of concern from dietary exposures to children, pregnant women or their fetus. Points of departure and endpoints are not being established for dietary exposures for this chemical.

Data Deficiencies

The toxicology database for sodium benzoate is incomplete but is adequate for risk assessment based on the toxicity studies and the low exposure potential for the proposed use patterns. Based on the 158W data requirements, there are several studies missing because those submitted were deemed unacceptable. Although FDA considers sodium benzoate GRAS by the oral route, this designation does not account for systemic effects that could occur via the inhalation route of exposure. Despite the missing information, the Agency can qualitatively assess this new AI based on use patterns, long time use, low hazard and the acceptable studies that were received. No additional data are needed at this time.

Because of the potential for occupational exposures via the inhalation route from open-pour of the product Kalaguard® SB, the Agency has evaluated particle size distribution data for this product and concluded that inhalation exposure to Kalaguard® SB should be assessed as a non-inhalable particle. If any additional registrations are received, evaluation of particle size and use rates and patterns will be necessary to determine if additional inhalation data are needed.

While the Agency lacks an acceptable study for neurotoxicity, other short and long-term studies submitted by the registrant and categorized as acceptable for qualitative purposes did not demonstrate neurotoxic effects below 1000 mg/kg/day (limit dose) (Deuel, 1954; Sodemoto, 1980; Ulrich, 1981). At this time, the Agency does not have concerns for systemic neurotoxicity from exposure to sodium benzoate and no additional neurotoxicity data are required.

The Agency lacks acceptable studies to support the requirements for prenatal developmental toxicity (OCSPP 870.3700) and for reproduction and fertility effects (OCSPP 870.3800). For the proposed uses, a prenatal development toxicity study would typically be required. However, exposure to the final treated articles (*i.e.,* cleaners, *etc.*) via the oral route is well below the level deemed GRAS by the FDA, and therefore not expected to show prenatal risk.

Toxicity Endpoint and Point of Departure Selections

Dietary/Oral

The proposed use as a materials preservative in household products could potentially result in food contact via countertops and other kitchen surfaces. Therefore, this use is considered an indirect food use.

The Agency is not establishing acute or chronic dietary points of departure and endpoints because the proposed maximum concentration in the final end-use product (*i.e.,* cleaning products) of 3% results in a total estimated daily dietary intake (TEDDI)[1] of 31,000 ppb (µg AI/kg food) or 0.0031% in food. When used as an antimicrobial agent, sodium benzoate can be in food and affirmed as generally recognized as safe (GRAS) by the FDA, at a level not to exceed 0.1% in food. In addition, the oral studies reviewed by the Agency demonstrated that toxic effects were observed at or above the limit dose (1000 mg/kg-bw/day).

Dermal

The Agency has reviewed two dermal studies submitted by the registrant to support the registration of this product. A 21-day dermal study performed in New Zealand rabbits (MRID 50680901) using benzoic acid (99.5%) showed dermal effects above the limit dose of 1000 mg/kg/day (specifically at 2500 mg/kg/day). In another study performed in Wistar rats using benzyl benzoate (≥ 99.0%; MRID 43566901), the animals showed adverse effects at the limit

[1] Assumes 100% transfer from surface to food and 4000 cm^2 surface area. Label includes up to 3% Sodium Benzoate in final product. Residue value (mg)= Active on surface * surface area * fraction transferred = (0.03*1 mg/cm2) *4000 cm^2*1=120 mg. Total Estimated Daily Dietary Intake (TEDDI) = (Residue value (mg)/1000) *Consumption Ratio/kg food consumed. For general population, Consumption Ratio = 1. TEDDI = 120 mg/1000*1/3.91 kg food consumed = 31,000 µg ai/kg food or 31,000 ppm. Food consumed are mean weights from NHANES WWEIA 2003-2008.

dose. Therefore, the Agency has determined that points of departure or endpoints do not have to be established for dermal exposures of this product.

Inhalation

While an acceptable non-guideline inhalation study is available, the effects seen at the highest dose tested (1.2 mg/L; body weight loss and mortality) were above the limit dose of 1.0 mg/L which is not relevant for risk assessment.

Dietary Exposure and Risk Assessment

Federal Food, Drug, and Cosmetic Act (FFDCA) Clearances

The US Food and Drug Administration (US FDA) lists sodium benzoate in 21 CFR §184.1733 as a direct food substance affirmed as GRAS. Table 3 below lists the specifics of this classification.

Table 3. Summary of FDA Clearances

21 CFR Section	Specifications	Use	Chemical	Maximum Residue Level
184.1733[1]	(c) The ingredient is used as an antimicrobial agent as defined in 170.3(o)(2) of this chapter, and as a flavoring agent and adjuvant as defined in 170.3(o)(12) of this chapter. (d) The ingredient is used in food at levels not to exceed good manufacturing practice. Current usage results in a maximum level of 0.1 percent in food. (The Food and Drug Administration has not determined whether significantly different conditions of use would be GRAS.)	Antimicrobial agent and flavoring agent and adjuvant	Sodium benzoate is the chemical benzoate of soda (C7H5NaO2), produced by the neutralization of benzoic acid with sodium bicarbonate, sodium carbonate, or sodium hydroxide	0.1% in food

1. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=184.1733

Food Exposure Profile

The proposed use as a materials preservative in household products could potentially result in indirect food contact via countertops and other kitchen surfaces. Therefore, this use is considered a food use. However, because the proposed product is intended for use as a materials preservative, no tolerance or exemption for is necessary.

Total Estimated Daily Dietary Intake (TEDDI) Assessment

In order to determine the residue level of sodium benzoate in food, the Agency calculated the total estimated daily dietary intake (TEDDI). The proposed maximum concentration in the final end-use product (*i.e.,* cleaning products) of 3% results in a TEDDI of 31,000 ppb (µg AI/kg food) or 0.0031% in food which is less than the maximum level of 0.1% in food considered GRAS by FDA.

Dietary Risk Assessment

Because there are no effects at the highest dose tested (1000 mg/kg/day) and the proposed use will result in concentrations of sodium benzoate significantly lower than the GRAS limit, the Agency has determined there are no dietary risks of concern.

Residential (Non-Occupational) Exposure/Risk Characterization

The proposed use of sodium benzoate as a materials preservative in household cleaners could result in short term inhalation and dermal handler and incidental oral post-application exposures from spraying, wiping, or mopping cleaners in the home. These exposures do not need to be assessed because toxicity endpoints were not selected for sodium benzoate due to low repeat dose toxicity.

Aggregate Exposure/Risk Characterization

Because toxicity endpoints were not selected for sodium benzoate due to low repeated dose toxicity, an aggregate assessment is not needed.

Cumulative Exposure/Risk Characterization

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to sodium benzoate and any other substances and sodium benzoate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that sodium benzoate has a common mechanism of toxicity with other substances. In 2016, EPA's Office of Pesticide Programs released a guidance document entitled, *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis* [https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework]. This document provides guidance on how to screen groups of pesticides for cumulative evaluation using a two-step approach beginning with the evaluation of available toxicological information and if necessary, followed by a risk-based screening approach. This framework supplements the existing guidance documents for establishing

common mechanism groups (CMGs)[2] and conducting cumulative risk assessments (CRA)[3]. During Registration Review, the Agency will utilize this framework to determine if the available toxicological data for sodium benzoate suggests a candidate CMG may be established with other pesticides. If a CMG is established, a screening-level toxicology and exposure analysis may be conducted to provide an initial screen for multiple pesticide exposure.

Occupational Exposure/Risk Characterization

An occupational exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, *etc*.) during use or to persons entering treated sites after application is complete. For sodium benzoate, there is potential exposure to occupational handlers during the application of sodium benzoate products for surface treatments using sprays, mops, or wipes. However, the toxicological criteria are not triggered and no subchronic toxicity endpoints are available to develop a quantitative risk assessment due to low toxicity. Therefore, an occupational risk assessment is not required.

ENVIRONMENTAL RISK ASSESSMENT

Environmental Fate

Sodium benzoate is the salt of benzoic acid and will immediately dissociate to form benzoic acid in an aqueous environment; therefore, the environmental fate data for sodium benzoate is essentially that of benzoic acid.

Benzoic acid does not undergo hydrolysis or photolysis. It has a pKa of 4.19, is expected to exist as a negatively-charged chemical species (anion) and is highly mobile in soil. Based on benzoic acid's vapor pressure ($7x10^4$ mm Hg), it is expected to be semi-volatile[4] under field conditions (dry non-absorbing surfaces). Sodium benzoate has been shown to be readily biodegradable in multiple studies, further supported by the OCSPP ready biodegradability guideline study (835.3110), which states that sodium benzoate is not recommended for use as a reference compound due to its biodegradability.

The proposed new use of sodium benzoate as an in-container materials preservative is expected to result in negligible environmental exposure to sodium benzoate or benzoic acid. Table 4 below lists the environmental data the registrants submitted to support the proposed new use of sodium benzoate.

[2] *Guidance for Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (USEPA, 1999)
[3] *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity* (USEPA, 2002)
[4] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-reporting-environmental-fate-and-transport#I_B_three

Table 4. Environmental Fate Data Submitted to Support the Proposed Uses of Kalaguard® SB

Guideline No.	Study Type	Citation (MRID)	Summary
835.2120	Hydrolysis	50471409	This is an excerpt from the OECD SIDS document stating that no hydrolysis is expected. The Agency agrees.
835.2240	Photodegradation in Water	50471410	No adsorption of light in the 290-800 nm range
835.3110	Ready Biodegradability	50471408	Acceptable waiver request, the Agency agrees that sodium benzoate is readily biodegradable
850.3300/ 850.6800	Activated Sludge Respiration Test (ASRI)	50471411	Literature study, IC_{50} > 1000 mg/L

Aquatic Exposure Modeling

Based on the proposed use of Kalaguard® SB as an in-container material preservative in industrial and household products, environmental exposure to sodium benzoate and benzoic acid is expected to be minimal. The majority of end-use products mentioned on the label are used indoors and will result in negligible environmental exposure (*i.e.*, products for furniture care, leather care, adhesives). A few products (*i.e.*, detergents, soaps, and shampoos) could go down the drain into a municipal wastewater treatment plant; however, environmental exposure is expected to be minimal. Any sodium benzoate or benzoic acid present are expected to biodegrade within the wastewater treatment plant, be diluted within the waste stream, and would not be concentrated in any specific geographic location.

Ecological Effects Data

Sodium benzoate and benzyl benzoate both dissociate to form benzoic acid in water; therefore, ecotoxicity data for benzoic acid and benzyl benzoate can be used to support this sodium benzoate registration.

The registrant has submitted open literature studies, excerpts, citations, waiver requests, and one guideline study in support of the proposed use of Kalaguard® SB as a material preservative. These documents have been reviewed and a summary of relevant information is available in Appendix C. One new algae study (MRID 50471418) has been used for endpoint selection below (Table 5).

The remaining endpoints selected come from previously published benzoic acid and benzyl benzoate documents including the ecotoxicity summary document for benzoic acid (US EPA, 2010b) and the *De Minimis* risk memo for the registration review of benzyl benzoate (US EPA,

2016). These endpoints indicate sodium benzoate is practically non-toxic to birds, moderately toxic to freshwater fish, and practically non-toxic to freshwater invertebrates. Additionally, it shows toxicity to aquatic plants at concentrations greater than 1 ppm.

Table 5. Ecological Effects Data

Receptor Group	Surrogate Species	Exposure Scenario	Test Material	Toxicity Endpoint	Toxicity Category	Reference
Birds	Mallard Duck (*Anas Platyrhynchos*)	Acute	Benzoic Acid	14-day LC_{50} >2510 mg/kg/day	Practically Non-Toxic	00148303
		Dietary	Benzoic Acid	8-day LC_{50} >5620 mg/kg/day	Practically Non-Toxic	00148304
	Bobwhite Quail (*Colinus Virginianus*)	Acute	Benzyl Benzoate	15-day LC_{50} >2000 mg/kg/day	Practically Non-Toxic	44033101
		Dietary	Benzyl Benzoate	8-day LC_{50} >5000 mg/kg/day	Practically Non-Toxic	44033102
		Dietary	Benzoic Acid	8-day LC_{50} >5620 mg/kg/day	Practically Non-Toxic	00148304
Freshwater invertebrates	Water Flea (*Daphnia magna*)	Acute	Benzoic Acid	48-h EC_{50} = >100 ppm	Practically Non-toxic	00147398
Freshwater Fish	Rainbow Trout (*Oncorhynchus mykiss*)	Acute	Benzyl Benzoate	96-hr LC_{50} =1.4 mg/L	Moderately Toxic	45209501
Aquatic Plant	Algae (*Pseudokirchneriella subcapitata*)	--	Sodium Benzoate	Yield: EC_{50} (72hr) = 24.8 mg/L (TWA) Growth Rate: EC_{50} (72hr) >30.5 mg/L (TWA)	--	50471418
TWA: Time Weighted Average						

Ecological Risk Characterization

Aquatic Risk Estimates

Due to the low aquatic exposure from the proposed use of sodium benzoate as an in-container material preservative and moderate to low toxicity to non-target aquatic organisms (including aquatic plants), risk to aquatic organisms are not of concern.

Terrestrial Risk Estimates

Due to the low terrestrial exposure from the proposed use of sodium benzoate and toxicity category to birds of "practically non-toxic", risk to non-target birds are not of concern. Although no data are available for pollinators, terrestrial exposure from the proposed use is expected to be negligible. Therefore, risks to pollinators are not expected.

Summary of Major Risk Presumptions

No major risk presumptions within the risk assessment for non-target organisms in the environment were identified for this proposed use of sodium benzoate as a material preservative.

Ecological Data Gaps

All ecotoxicity data requirements have been satisfied for the proposed registration of sodium benzoate as an in-container material preservative.

LISTED SPECIES OF CONCERN

Due to the low environmental exposure expected from the use pattern, the environmental fate properties of the compound, and moderate to low toxicity to non-target species, no reasonable expectation of direct or indirect adverse effects to threatened and endangered species nor adverse modification of any designated critical habitat for such species is expected from the proposed use of sodium benzoate as an in-container material preservative in industrial and household products.

Thus, EPA is making a "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required for the proposed use of sodium benzoate. Should the use pattern or usage information relied upon within this assessment change, then the Agency may need to re-evaluate this determination.

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APPENDIX A: Proposed Product Label

Master Label: Version 061120
Kalaguard® SB

Active Ingredient:
Sodium Benzoate.....100%

KEEP OUT OF REACH OF CHILDREN
WARNING

EPA Registration No. 91212-R

EPAEstablishment No. {to be inserted} Batch Code: {to be inserted}
[Made for][Sold][Distributed][by]:
Emerald Kalama Chemical, LLC
1499 SE Tech Center Place, Suite 300 Vancouver, WA 98683
[phone] 360-954-7100

[Kalaguard® is a registered trademark of Emerald Kalama Chemical, LLC]
[Emerald Kalama Chemical B.V. is a wholly owned subsidiary of Emerald Kalama Chemical, LLC]

FIRST AID
If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice.
Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. For emergencies, call 1-800-255-3924.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through the skin. Do not get in eyes or on clothing. Avoid contact with skin. Wear safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

This product is to be used as an in-container preservative for controlling problem causing organisms in industrial and household products including detergents, fabric softeners, soaps, liquid cleaners, furniture care, floor care, cleaning wipes, shampoos, leather care, coatings, inks, adhesives, silicone emulsions, surfactants and other water-based products requiring preservation. The table below provides recommended dose levels for the noted categories of water-based solutions and products. All final product formulations should be validated for microbial and fungal control.

Type of product	**Representative Products**	**Dose Range**
Cationic Emulsions	Fabric softeners, surfactants, cationic emulsions	0.05% - 3.0%
Anionic Detergents	Detergents, soaps, liquid cleaners, shampoos, surfactants, anionic detergents	0.25% - 3.0%
Non-ionic Emulsions	Soaps, liquid cleaners, furniture care products, floor care products, leather care products, coatings, adhesives, silicones, surfactants, inks, non-ionic emulsions	0.5% - 3.0%
Anionic Detergent Wipes	Wet/Premoistened Wipes	0.5% - 3.0%
Non-Ionic Emulsion Wipes	Wet/Premoistened Wipes	0.5% - 3.0%

Kalaguard SB is to be added to the product at a maximum level of 3% by weight in order to prevent and control microbial growth. Add Kalaguard SB at any convenient time during the manufacturing process.

No finished product containing Kalaguard SB may make public health claims relating to antimicrobial activity without EPA pesticide registration. This product does not protect the user or any treated article against disease causing bacteria, viruses, or fungi. Products preserved with Kalaguard SB for the sole purpose of preventing product decomposition and/or microbial spoilage are exempt from registration as described in 40 CFR 152.25(a).

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Product Storage: Keep container closed when not in use. Store in a cool, dry and well-ventilated area. Product is hygroscopic and will absorb moisture.

Product Disposal: Waste resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag during use. Offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local officials.

Text in [brackets] is optional. Text in {braces} is informational to the reviewer. Version 061120

APPENDIX B: Toxicology Profile

No acute category determinations have been made for sodium benzoate at this time. Instead, the acute toxicity determinations for benzoic acid were used (USEPA 2010a).

Table B1. Acute category determinations for Benzoic Acid[a]

Acute Toxicology Profile of 99.95% Benzoic Acid	
Exposure Route	**Category**
Oral	III
Dermal (Rabbit)	IV
Inhalation	IV
Dermal Irritation (Rabbit)	III
Eye Irritation	I
Dermal Sensitization (Guinea Pig)	Not a dermal sensitizer

a. USEPA 2010a

Table B2. Summary of Toxicological Doses and Endpoints for Sodium Benzoate

Exposure/ Scenario	Point of Departure	Uncertainty Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute or Chronic Dietary	Acute or chronic dietary points of departures do not have to be established as sodium benzoate is GRAS and used in food preservation up to 0.1% (by weight) in food.			
Incidental Oral (Any duration)	Incidental oral (any duration) points of departures do not have to be established as sodium benzoate is designated by FDA as GRAS (Generally Recognized as Safe) at up to 0.1% in food, far greater than the calculated TEDDI of 0.0031% or 31,000 ppb (µg AI/kg) in food.			
Dermal Short- (1-30 days), Intermediate Term (1-6 months), and Long Term (>6 months)	Dermal points of departure are not being selected for occupational uses as workers should wear personal protective equipment to protect from potentially irritating effects of sodium benzoate.			
Inhalation Short- Term (1-30 days)/Intermediate-Term (1-6 months/Long-Term (>6 months)[A]	NOAEL= 1000 mg/kg/day	UF_A = 10x UF_H = 10x	LOC for MOE = 100[A]	MRID 50471420 (1954) Deuel. 90 Day oral toxicity study. No adverse effects observed at the limit dose (1000 mg/kg/day). MRID 50471427 (1993) Fujitani. Short-term effect of sodium benzoate in F344 rats and B6C3F1 mice Rat: Decrease in thymus weights observed above 1000 mg/kg/day, the limit dose. Measurements on thymus hormones were not performed. Mouse: No adverse effects were observed at the lowest dose tested (3120 mg/kg/day). MRID 50471427 (1980) Sodemoto, Y. and M. Enomoto. Six-week oral dietary study. No adverse effects observed at the limit dose (1000 mg/kg/day).

Exposure/ Scenario	Point of Departure	Uncertainty Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Cancer (oral, dermal, inhalation)	The National Toxicology Program (NTP) conducted two-year toxicology and carcinogenesis studies on benzyl alcohol (1989), benzaldehyde (1990), and benzyl acetate (1993) and found no definitive conclusions of carcinogenicity could be made.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). MOE = margin of exposure. LOC = level of concern.

[A] A mammalian repeat-dose inhalation toxicity study is not being required at this time by the Agency. The oral POD selected for inhalation exposures is conservative and protective of any potential adverse effects that may occur via the inhalation route. The exposure potential is considered to be low based on the formulation into non-inhalable particles. The resulting MOEs> 1000, eliminating the need to require an inhalation toxicity study and for an uncertainty factor for the lack of a route-specific study.

The following studies are those used by the Agency to support a qualitative risk assessment. In order to support the toxicology data requirements outlined in 158W, the registrant submitted various open literature studies, excerpts from summary documents from another organization (*e.g.*, OECD SIDS), citations for studies deemed acceptable within previous Agency documents, unpublished studies, and waiver requests. However, not all the submissions were deemed acceptable according to Agency guidance.

Table B2. Studies to Support Proposed Registration of Kalaguard® SB[a]

Non-Acute Toxicity Profile for Sodium Benzoate		
Guideline number/Study Type/Test Substance (% AI)	**MRID number (Year)/Citation/Classification/Doses**	**Results**
Subchronic		
570.3100 90-day oral toxicity study Rat Dietary Sodium benzoate (purity not reported)	MRID 50471420 (1954) Deuel, H.J., *et al* Sorbic acid as Fungistat agent for foods. I. Harmlessness of sorbic acid as a dietary component. *Food Research* 19:1-12 Qualitative/Non-Guideline 0, 1, 2, 4, 8% (0, 640, 1320, 2620, 6290 mg/kg/day)	No adverse effects observed at the limit dose (1000 mg/kg/day).

570.3100 10-day oral toxicity study Rat and Mouse Dietary Sodium benzoate (purity not reported)	MRID 50471427 (1993) Fujitani, T. Short-term effect of sodium benzoate in F344 rats and B6C3F1 mice. *Toxicology Letters* 69: 171-179. Qualitative/Non-guideline Rat: 0, 1.81, 2.09, 2.4% (0, 905, 1045, 1200 mg/kg/day) Mouse: 0, 2.08, 2.5, 3% (0, 3120, 3750, 4500 mg/kg/day)	Rat: Decrease in thymus weights observed above 1000 mg/kg/day, the limit dose. Measurements on thymus hormones were not performed. Mouse: No adverse effects were observed at the lowest dose tested (3120 mg/kg/day).
570.3100 6-week oral toxicity study Rat Dietary Sodium benzoate (purity not reported)	MRID 50471427 (1980) Sodemoto, Y. and M. Enomoto. Report of carcinogenesis bioassay of sodium benzoate in rats: Absence of carcinogenicity of sodium benzoate in rats. *Journal of Environmental Pathology and Toxicology* 4: 87-95 Qualitative/Non-guideline 0, 0.5, 1, 2, 4, 8% in diet (0, 250, 500, 1000, 2000, 4000 mg/kg/day)	No adverse effects observed at the limit dose (1000 mg/kg/day).
870.3200 21-Day dermal toxicity study Rabbit 99.5% benzoic acid	MRID 50680901 (1981). Laveglia, J. 21-day dermal toxicity study in rabbits. Unpublished Unacceptable/Non-guideline 0, 100, 500, 2500 mg/kg/day	Not acceptable
870.3250 90-Day dermal toxicity study Rabbit ≥99.9% benzyl benzoate	MRID 43566901 (1994). Schmid, H., *et al*. Subchronic 90-day repeated dose dermal toxicity study with benzyl benzoate, interim report. Unpublished Acceptable/Guideline 0, 40, 200, 1000 mg/kg/day	Irritation effects were not observed at the limit dose of 1000 mg/kg/day. Adverse systemic effects were not observed at any dose.
870.3465 90-Day Inhalation toxicity in the rat Rat Benzoic Acid	MRID 50680903 (1981) Ulrich. Four Week Subacute Inhalation Toxicity Study of Benzoic Acid in Rats Acceptable/Non-guideline 0, 0.025, 0.25, 1.2 mg/L	Weight loss and mortality seen at 1.2 mg/L. Portal of entry effects were not evaluated.

Chronic		
Guideline number/Study Type/Test Substance (% AI)	MRID number (Year)/Citation/Classification/Doses	Results
570.4100 Chronic/ Carcinogenicity study 18-24 month dietary study Rat Sodium benzoate (purity not reported)	MRID 50471427 (1980) Sodemoto, Y. and M. Enomoto. Report of carcinogenesis bioassay of sodium benzoate in rats: Absence of carcinogenicity of sodium benzoate in rats. *Journal of Environmental Pathology and Toxicology* 4: 87-95 Qualitative/Non-guideline 0, 1, 2% in diet (0, 500, 1000 mg/kg/day)	No evidence of carcinogenicity.
870.4300 Carcinogenicity Two-year gavage Rat 99% Benzyl alcohol	MRID 43148604 (1989) Dieter, M. Toxicology and Carcinogenesis Studies of Benzyl Alcohol in F344/N Rats and B6C3F1 Mice. National Toxicology Program. Acceptable/non-guideline 0, 200 or 400 mg/kg/day	NOAEL = 400 mg/kg/day LOAEL was not detected. The only treatment-related significant effects occurred in the forestomach which are not relevant for this risk assessment. No evidence of carcinogenicity.
870.4300 Carcinogenicity Two-year gavage Mouse 99% Benzyl alcohol	MRID 43148604 (1989) Dieter, M. Toxicology and Carcinogenesis Studies of Benzyl Alcohol in F344/N Rats and B6C3F1 Mice. National Toxicology Program. Acceptable/non-guideline 0, 100 or 200 mg/kg/day	NOAEL = 100 mg/kg/day LOAEL = 200 mg/kg/day based on increased incidence of corpora amylacea in the brain of females (50% vs. 28% controls). No evidence of carcinogenicity (TXR 0057982).
870.4300 Carcinogenicity Two-year gavage Rat 99% Benzaldehyde	51021401 (1990) Bishop, J. Toxicology and Carcinogenesis Studies of Benzaldehyde in F344/N Rats and B6C3F1 Mice. National Toxicology Program. Acceptable/non-guideline 0, 200 or 400 mg/kg/day	NOAEL = 200 mg/kg/day LOAEL = 400 mg/kg/day based on decreased survival (52% vs. 80% controls). No evidence of carcinogenicity.

870.4300 Carcinogenicity Two-year gavage Mouse 99% Benzaldehyde	51021401 (1990) Bishop, J. Toxicology and Carcinogenesis Studies of Benzaldehyde in F344/N Rats and B6C3F1 Mice. National Toxicology Program. Acceptable/non-guideline 0, 200 or 400 mg/kg/day	NOAEL = 400 mg/kg/day LOAEL was not detected. Forestomach hyperplasia (not relevant to humans) was seen in females at 200 mg/kg/day. No evidence of carcinogenicity relevant to humans. Increased squamous cell papillomas and hyperplasia of forestomach seen in females at 200 and 400 mg/kg/day.
Developmental Toxicity and Reproduction		
Guideline number/Study Type/Test Substance (% AI)	MRID number (Year)/Citation/Classification/Doses	Results
870.3700 Prenatal developmental toxicity Mouse, Rat, Hamster, Rabbit Sodium benzoate (purity)	MRID 50471432 (1972) Food and Drug Laboratories. Teratologic Evaluation of FDA 71-37 (Sodium Benzoate) in Mice, Rats, Hamsters and Rabbits Unacceptable/Non-guideline Mouse and Rat: 0, 1.75, 8, 38, 175 mg/kg/day Hamster: 0, 3, 14, 65, 300 mg/kg/day Rabbit: 0, 2.5, 12, 54, 250 mg/kg/day	Not acceptable
870.3800 Reproduction and fertility effects Rat (unknown species) Benzoic acid Sodium benzoate Purity not reported for either	MRID 50471427 (unk). Kiekebusch, W and K. Lang. The tolerability of benzoic acid in chronic feeding experiments. Unknown citation, not originally in English. Unacceptable/Non-guideline 0, 0.5, 1% in diet benzoic acid 5% in diet sodium benzoate	Not acceptable
870.6200/6300 Neurotoxicity and Developmental Neurotoxicity Rat Sodium benzoate (purity not reported)	MRID 50471430 (1985) Crane, S.C., and P.A. Lachance. The Effect of Chronic Sodium Benzoate Consumption on Brain Monamines and Spontaneous Activity in Rats. Nutrition Reports International. 32: 169-177 Unacceptable/Non-guideline 0, 0.1, 0.5, 1.0% in diet	Not acceptable
Mutagenicity		
Guideline number/Study Type/Test Substance (% AI)	MRID number (Year)/Citation/Classification/Doses	Results

870.5100 Reverse mutation assay Sodium benzoate (purity not reported)	MRID 50471433 (1991) Prival, M.J., *et al.* Bacterial mutagenicity testing of 49 food ingredients gives very few positive results. *Mutation Research* 260: 321-329 Qualitative/Non-guideline 0, 0.033, 0.1, 0.33, 1.0, 3.3, 10 mg/plate	Negative in the reverse mutation assay with and without S9 fraction metabolic activation.
870.5100 Reverse mutation assay Benzoic acid 99.5% AI	MRID 50471433 (1979) Haworth, S.R., *et al*. *Salmonella/*mammalian-microsome plate incorporation mutagenesis assay of velsicol chemical corporation compound benzoic acid 99.5% (GC) Lot #52829055 Study #580-192-1-78 (MRI #192). Acceptable/Guideline 20, 100, 520, 1000, 2000 µg/plate	Negative in the reverse mutation assay with and without S9 fraction metabolic activation.
870.5300 *In vitro* mammalian gene mutation Benzyl Alcohol Benzaldehyde Benzyl Acetate	No MRID NTP 1989 Benzyl Alcohol No MRID NTP 1990 Benzaldehyde No MRID NTP 1993 Benzyl Acetate Acceptable/Guideline	Positive in mouse L5178Y lymphoma assay. Positive in CHO assay.
870.5300 *In vitro* mammalian gene mutation Benzaldehyde	MRID 50471434 (1991) McGregor, D.B., *et al.* Responses of the L5178Y mouse lymphoma cell forward mutation assay. V: 27 coded chemicals. *Environmental and Molecular Mutagenesis* 17: 196-219. Unacceptable	Not acceptable
870.5375 *In vitro* mammalian gene mutation	MRID 50471435 (1974) Mutagenic Evaluation of Compound FDA 71-37, Sodium Benzoate. Unpublished study prepared by Litton Bionetics. 95 pp. Acceptable/Non-guideline 0, 20, 200 µg/ml	Negative in the cytogenetic assay.
870.5385/870.5450 *In vivo* cytogenetics (Dominant lethal assay and cytogenetic assay) Rat	MRID 50471435 (1974) Mutagenic Evaluation of Compound FDA 71-37, Sodium Benzoate. Unpublished study prepared by Litton Bionetics. 95 pp. Acceptable/Non-guideline 0, 50, 500, 5000 mg/kg	Negative in the dominant lethal assay and the cytogenetic assay.

Special		
Guideline number/Study Type/Test Substance (% AI)	MRID number (Year)/Citation/Classification/Doses	Results
870.7485 Metabolism and pharmacokinetics Human	MRID 50471436 (1991) Kubota, K, and T. Ishizaki. Dose-dependent pharmacokinetics of benzoic acid following oral administration of sodium benzoate to humans. Eur J. Clin Pharmacol 41: 363-368 Acceptable/Non-guideline	Both benzoic acid and sodium benzoate are excreted as hippuric acid in the urine in a rate-limited fashion

a. Please note some MRIDs contain multiple studies/citations. Only those that were used are listed in the table.

References:

D454105. U.S. Environmental Protection Agency. (2019). Data Evaluation Records (DERs) and Summaries for Ecological Effects Data Submitted in Support of the New AI Sodium Benzoate. Product 91212-R Kalaguard™ SB. Date: Aug 27, 2019.

APPENDIX C: Ecotoxicity Data Cited

In order to support the ecotoxicity data requirements outlined in 158W, the registrant submitted various open literature studies, excerpts from other organization's review documents (*i.e.*, OECD SIDS[5]), previous Agency documents, one guideline study, and waiver requests. These documents have been reviewed (DP 453974) and a summary of their contents and endpoints are outline below in table C1.

Table C1: Ecological Effects Data Submitted to Support the Proposed Uses of Kalaguard SB

Guideline No.	Study Type	Citation	Summary
Nontarget Organism and Plant Discussion Volume		MRID 50471412	Summary of submitted documents
850.2100	Acute Avian Oral Toxicity	MRID 50471413	Open literature. Test substance benzoic acid. LD_{50} is >100 mg/kg for redwing blackbirds and >100 mg/kg in Starlings (*Sturnus vulgaris*). (Supports determination: No worse than moderately toxic to birds)
			Cited MRID 00148303 - Acceptable Guideline Study. LD_{50} of >2510 mg/kg benzoic acid (Practically non-toxic to birds)
850.2200	Avian Dietary Toxicity	MRID 50471417	Cited ECOTOX studies with IDs 073655 and 73655 (same study as MRID 00148304) which used 95.9% benzoic acid. 8-day dietary LC_{50} values are >5620 mg/kg-diet for both Mallard duck (*Anas platyrhynchos*) and Bobwhite quail (*Colinus virginianus*). (Supports determination: Practically non-toxic to birds)
850.1075	Acute Freshwater Fish Toxicity	MRID 50471415	Open literature. Test substance "benzoic acid, sodium salt" 96-hr LC_{50} is 484 mg/L for fathead minnow (*Pimephales promelas*) (Supports determination: Practically non-toxic to freshwater fish)
			Excerpt from OECD SIDS document. 96-hr LC_{50} is 47.3 mg/L for rainbow trout (*Salmo gairdneri*) (Supports determination: Slightly toxic to freshwater fish)
850.1400	Fish Early Life Stage Toxicity	MRID 50471412	Waiver requested based on low toxicity, ready biodegradability, and low bioaccumulation potential. Waiver rationale is satisfactory.
850.1010	Acute Freshwater Invertebrate Toxicity	MRID 50471414	Open literature. Test substance sodium benzoate. 96-hr LC_{50} for all organisms including daphnids (*Daphnia magna*) and fathead minnow (*Pimephales promelas*) were >100 mg/L. (Supports determination: Practically non-toxic to freshwater fish and invertebrates)

[5] The Organization for Economic Cooperation and Development Screening Information Data Sets (OECD SIDS)

850.1300	Aquatic Invertebrate Life-cycle/ Daphnid Chronic Toxicity Test	MRID 50471416	Open literature. Test substance sodium benzoate. Not a chronic toxicity test, but rather an acute toxicity test. Therefore, does not satisfy the guideline. However, additional chronic data not needed due to low toxicity, ready biodegradability, and low bioaccumulation potential.
850.5400 (850.4500)	Aquatic Plant Growth (Algal) Tier II (Dose Response)	MRID 50471418	OECD 201 Study. Test substance sodium benzoate. Test organism: *Pseudokirchneriella subcapitata* Yield: EC_{50} (72hr) = 24.8 mg/L (TWA) NOEC (72hr) = 0.09 mg/L (TWA) Growth Rate: EC_{50} (72hr) >30.5 mg/L (TWA) NOEC (72hr) = 0.09 mg/L (TWA) (**Supplemental** study and shows low toxicity to plants)

TWA= Time Weighted Average

References:

DP 453974. U.S. Environmental Protection Agency. (2019). Data Evaluation Records (DERs) and Summaries for Ecological Effects Data Submitted in Support of the New AI Sodium Benzoate. Product 91212-R Kalaguard SB. Date: October 7, 2019.

MRID 50471412. Herber, T. (2017) Sodium Benzoate: Nontarget Organism and Nontarget Plant Discussion Volume. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 6pp.

MRID 50471413. Herber, T. (2017) Sodium Benzoate: Acute Avian Oral Toxicity. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 36pp.

MRID 50471414. Herber, T. (2017) Sodium Benzoate: Acute Freshwater Invertebrates Toxicity. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 16pp.

MRID 50471415. Herber, T. (2017) Sodium Benzoate: Acute Freshwater Fish Toxicity. Unpublished study prepared by Scientific & Regulatory Consultants. 37pp.

MRID 50471416. Herber, T. (2017) Sodium Benzoate: Daphnid Chronic Toxicity Test. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 12pp.

MRID 50471417. Herber, T. (2017) Sodium Benzoate: Avian Dietary Toxicity. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 8pp.

MRID 50471418. Herber, T. (2017) Sodium Benzoate: Aquatic Plant Growth (Algal) Tier II (Dose Response). Project Number: 493446. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. June 17, 2010. 41pp.